IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

HARRY KEEN, III, *Plaintiff*	:	**CIVIL ACTION**
v.	:	
C.R. BARD, INC., *et al.*, *Defendants*	:	**No. 13-5361**

MEMORANDUM

PRATTER, J. AUGUST 17, 2020

Harry Keen, III received a G2X inferior vena cava (IVC) filter—a prescription-based medical device placed in the largest vein leading to the heart in order to prevent blood clots—manufactured by C.R. Bard, Inc. and Bard Peripheral Vascular, Inc.[1] Approximately a year and three months after implantation, Mr. Keen's filter fractured, necessitating removal. Although a physician was unable to retrieve the fractured filter on the first attempt, all but two pieces of the filter which remain in a stable position were eventually retrieved. Mr. Keen brings this product liability action, alleging that Bard defectively designed and manufactured the G2X filter that was implanted in him and failed to provide adequate warning of the filter's complications. Bard moves for summary judgment in its favor as to all of the claims.

For the reasons detailed below, the Court grants summary judgment in favor of Bard as to the strict liability and breach of implied warranty of merchantability claims, denies summary judgment as to the negligence and negligence misrepresentation claims, and reserves its determination as to punitive damages for a later date.

[1] This Memorandum refers to Defendants collectively as "Bard."

BACKGROUND

I. Procedural Background

Bard's entire product line of retrievable IVC filters has been the subject of a multidistrict litigation created in 2015 and presided over by Judge David Campbell of the District of Arizona. *See in re Bard IVC Filters Prods. Liab. Litig.*, MDL No. 15-2641 (D. Ariz.). This particular case was transferred to the multidistrict litigation in 2015 and returned to this Court in 2019. Mr. Keen brings negligence and strict products liability claims based on manufacturing, design, and failure-to-warn theories, a breach of implied warranty of merchantability claim, a negligent misrepresentation claim, and he also seeks punitive damages, among other damages.

Now, Bard requests the Court to grant summary judgment in its favor as to all of Mr. Keen's claims. In addition to reviewing the parties' briefing and substantial evidentiary submissions pertaining to Bard's motion, the Court also ordered supplemental briefing concerning the admissibility of facts and evidence Mr. Keen "incorporated by reference," and held oral argument on the motion, following which the Court permitted the parties to submit supplemental briefing.

II. Factual Background

A. General Information About IVC Filters and the G2X Filter

The Bard G2X filter is a prescription medical device implanted in the IVC. The IVC is "the main vessel returning blood from the lower half of the body to the heart." *Cason v. C.R. Bard, Inc.*, No. 12-1288, 2015 WL 9913809, at *1 (N.D. Ga. Feb. 9, 2015). Generally, trauma patients face the risk of developing deep vein thromboses, which can result in a patient suffering from a potentially life-threatening pulmonary embolism. IVC filters are intended to help prevent blood clots from reaching the lungs and causing a pulmonary embolism. After implantation, all IVC

filters, including the G2X filter, carry risks of tilt, migration, puncture, fracture, and irretrievability.

B. Mr. Keen's Experience with the G2X Filter Implanted in his IVC

Mr. Keen was involved in a motorcycle accident on June 14, 2020, and, as a result, suffered multiple skull fractures and severe traumatic brain injury. Eight days later, Mr. Keen's physician, Dr. David Sacks, placed a Bard G2X filter in Mr. Keen's IVC as a prophylactic measure to prevent a pulmonary embolism. Dr. Sacks chose to use the G2X filter for Mr. Keen based on his clinical experience with the filter and his assessment of Mr. Keen's condition. Dr. Sacks intended that the G2X filter implanted in Mr. Keen would be used temporarily and retrieved in the future. Because it was unclear how long Mr. Keen would need the filter, Dr. Sacks thought that the G2X filter was preferable to the Gunther Tulip filter, the Greenfield filter, and the Simon Nitinol filter.[2]

On September 15, 2011, Dr. Karekin Cunningham performed a percutaneous procedure[3] in an attempt to retrieve the G2X filter implanted in Mr. Keen. During this retrieval procedure, Dr. Cunningham discovered that two of the filter struts had fractured and that the filter was tilted. Dr. Cunningham was unable to retrieve the filter on this date "secondary to lack of appropriate inventory and retrieval techniques." Reading Hosp. Med. Records, Ex. B (Doc. No. 60-2).

On October 21, 2014, Dr. Frank Lynch performed a second percutaneous procedure on October 21, 2014 to retrieve the G2X filter. Dr. Lynch retrieved the filter and most of the fractured components except for a "leg foot process" and "half of a filter leg," both of which were embedded in the wall of Mr. Keen's IVC. Penn State Hershey Med. Center Med. Records, Ex. F (Doc. No.

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[2] The Gunther Tulip filter, a retrievable filter, is recommended to be retrieved within 90 days, whereas the G2X filter can be retrieved after a longer duration of time. Moreover, the Greenfield filter and Simon Nitinol filter are both permanent filters.

[3] A percutaneous procedure is a needle-puncture of the skin, as opposed to an open surgical procedure.

60-6).

Mr. Keen alleges that he suffered from various complications, including filter fracture, tilt, perforation, and irretrievability of the fragments. Between the time Mr. Keen's filter was explanted in 2014 and the date of his last deposition in November 2019, he has not seen any doctors due to abdominal, back, or chest pain for an evaluation of the filter struts retained in his body. It appears that no doctor has recommended image monitoring of the filter struts still in his body. Mr. Keen understands that the filter struts are in stable position.

C. The Evolution of Bard IVC Filters

Bard distributed the Simon Nitinol filter for Nitinol Medical Technologies in the United States from at least as early as 1992 to 2001, when Bard purchased all the rights for the Simon Nitinol filter. In conjunction with Nitinol Medical Technologies, Bard developed a modified design of the Simon Nitinol filter known as the Recovery filter. The Recovery filter was intended to be removed, optionally, from the body. Bard obtained clearance from the Food and Drug Administration to market the Recovery filter through the 510(k) process as a permanent device in November 2002, and for optional retrieval in July 2003. The FDA grants 510(k) clearance "where the device is as safe and effective as a [predicate device] and does not raise different questions of safety and efficacy than the predicate device." *In re Bard IVC Filters Prods. Liab. Litig.*, 289 F. Supp.3d 1045, 1048 (D. Ariz. 2018) (citation omitted).

Bard modified the Recovery filter to develop the G2 filter. Bard developed an entire line of G2 filters, which includes the G2, G2 Express, and G2X filters. The FDA granted 510(k) clearance for retrievable use of the G2 filter in January 2008. The FDA also cleared the G2X filter

through the 510(k) process.[4] The only difference between the G2 filter and the G2X filter is a snare retrievable hook that Bard added to the G2X filer. Bard then developed the Eclipse filter, which is an electropolished[5] version of the G2X filter. The FDA cleared the Eclipse filter in January 2010 through the 510(k) process, approximately six months prior to the date that the G2X filter was implanted in Mr. Keen.

Mr. Keen submits a considerable amount of evidence concerning the various problems and complications associated with multiple Bard filters and Bard's apparent knowledge of such issues. In sum, Mr. Keen stresses that Bard's design and manufacturing of IVC filters were defective, including the G2X filter, which purportedly fracture, migrate, tilt, and perforate in patients' IVCs at rates significantly higher than other IVC filters. He also claims Bard failed to provide adequate warning of these complications. For the sake of brevity, the Court focuses on the evidence Mr. Keen relies upon in his briefing as they are, in turn, also addressed in defense of his claims from the challenge by Bard in its motion.

D. Information Bard Provided to Dr. Sacks

Dr. Sacks testified that he relies on "the manufacturer to tell [him] as much information as [it] ha[s] available that would be relevant to [his] placing the filter[,]" Sacks Dep. at 96:23-97:1 (Doc. No. 97-3), and that he expects the manufacturer to provide information concerning known adverse events with a product, *Id.* at 97:17-20. Bard provided both written and oral communications to Dr. Sacks concerning the G2X filter implanted in Mr. Keen.

Concerning the written communication, the G2X filter implanted in Mr. Keen was

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[4] Although the FDA clearance letter that Bard received was not submitted as part of the summary judgment record, Bard submitted it in support of its opposition to a motion *in limine*. For reference only, the FDA cleared the G2X filter in October 2008.

[5] Electropolishing is a manufacturing process intended to smooth out metal surfaces.

accompanied by an "Instructions for Use" document. Under the two bolded headings "**Warnings**" and "**Potential Complications**," the Instructions for Use warned physicians that:

> "Filter fractures are a known complication of vena cava filters. There have been some reports of serious pulmonary and cardiac complications with vena cava filters requiring the retrieval of the fragment utilizing endovascular and/or surgical techniques";
>
> "Movement, migration or tilt of the filter are known complications of vena cava filters";
>
> "Perforation or other acute or chronic damage of the IVC wall"; and
>
> "It is possible that complications such as those described in the 'Warnings', 'Precautions', or "Potential Complications' sections of these Instructions for Use may affect the recoverability of the device[.]"

June 2009 Instructions for Use, Ex. A (Doc. No. 60-1). Dr. Sacks does not recall if he read the Instructions for Use before treating Mr. Keen.

As for the oral communications, after stating his concerns about the Recovery filter to the Bard sales representative, Dr. Sacks recalls being "told that the G2 would address those problems of fracture and migration. I don't recall that the G2X had substantial differences from the function of the G2 other than the hook at the apex." Sacks Dep. at 107:5-10 (Doc. No. 97-3). Dr. Sacks further testified that a difference of fracture rate of one percent (1%) between IVC filters "would probably not have made a difference" as to his decision-making when choosing a particular filter. *See id.* at 107:11-108:12.

E. Evidentiary Notes

Much of the evidence Mr. Keen hopes to use in defending against Bard's motion is intended to highlight complications associated with Bard's IVC filters. The Court acknowledges that the parties raise a number of objections to each other's statements of facts and record citations. After thoroughly filtering the evidentiary issues raised by both parties, the Court will briefly address

only the most pertinent evidentiary issues.

In response to Bard's statement of facts, Mr. Keen included 88 "additional facts" and stated that he "incorporate[s] by reference Plaintiffs' Omnibus Separate Statement of Facts common to *Benzing v. C.R. Bard, Inc., et al.*, [No. 2013-054323] and *In re: Bard IVC Filters Products Liability Litigation*, [No. 15-2641]." Pl.'s Resp. to Def.s' Statement of Material Facts at ¶ 43 (Doc. No. 72). Bard argues that the Court should not only disregard but also strike Mr. Keen's "additional facts" and the "incorporated omnibus" statements of facts because they do not concern the G2X filter, Mr. Keen, or the complication of filter fracture that occurred in this case. Bard further contends that "incorporating" these additional facts violates Federal Rule 56 of Civil Procedure and the Court's pretrial procedures concerning how to respond to a movant's statements of material fact. Mr. Keen explained that he filed the omnibus statement of facts from the multidistrict litigation and the accompanying 121 exhibits only as a means "to preserve the numbering scheme that was used in the MDL filing for the convenience" of the parties. Pl.'s Supp. Briefing at 3-4 (Doc. No. 109).

Having no reason to doubt Mr. Keen's counsel's explanations for the effort to short-cut the paper-work, the Court is cognizant of the inherent organizational difficulties in submitting such a voluminous record for an action which was consolidated in a multidistrict litigation for pre-trail purposes. It is also confident that it is capable of making sense of Mr. Keen's evidentiary submissions. Thus, the Court declines Bard's request to categorically strike any paragraphs of or exhibits accompanying Mr. Keen's "additional facts" and "omnibus facts," acknowledging that doing so would essentially eviscerate Mr. Keen's entire response in opposition on the altar of the sanctity of procedure. There being no record here of a repeated disrespect of procedure, the Court will move on to consider the merits of the parties' positions.

The Court similarly rejects Bard's proposition that references to predicate filters, such as the Recovery filter, have no bearing on its motion for summary judgment. The Recovery is a predicate device to the G2, and, as explained above, the only difference between the G2 and the G2X is a snare retrievable hook added to the G2X. Because predicate filters led to the development of the G2X filter, it is certainly reasonable to consider that evidence concerning a predicate filter could assist a trier of fact in determining the safety or harmfulness of the G2X filter.

The Court does, however, have a serious reservation about some data relied upon by the parties. First, the Court will refrain from relying on MAUDE data[6] as a basis for evaluating accurate complication rates for purposes of ruling on Bard's motion for summary judgment.[7] Notably, the MAUDE Database website explains that "MAUDE data is not intended to be used either to evaluate rates of adverse events or to compare adverse event occurrence rates across devices." MAUDE Database Webpage 1, Ex. A (Doc. No. 118-1). The FDA's MAUDE disclaimer further explains the limitations of MAUDE data, "including the potential submission of incomplete, inaccurate, untimely, unverified, or biased data. In addition, the incidence of prevalence of an event cannot be determined from this reporting system alone due to under-reporting of events, inaccuracies in reports, lack of verification that the device caused the reported event, and lack of information about frequency of device use." MAUDE Database Webpage 2, Ex. 2 (Doc. No. 118-2).[8]

Second, the Court will not consider data postdating Mr. Keen's interactions with the

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[6] "MAUDE" data refers to information concerning adverse events and medical device reporting published on the FDA's public, searchable database.

[7] Bard must submit a motion *in limine* if it seeks to exclude MAUDE data at trial.

[8] However, the Court notes that numerous courts, including Judge Campbell in the multidistrict litigation, have found that experts may rely on MAUDE data in forming opinions. *See, e.g., In re: Bard IVC Filters Prods. Liab. Litig.*, No. 15-2641, 2018 WL 495607, at **5-6 (D. Ariz. Jan. 22, 2018).

medical world to the extent it is relied upon to discern Bard's knowledge prior to the implantation or the harmfulness of the filter at the time at issue. Thus, the Court rejects Bard's contention that the complication rates it relies on, which incorporates data dating from as recently as January 2017 and provides no means to discern rates for the relevant time period, *i.e.*, before the 2010-2011 time period, to provide dispositive evidence necessitating the Court's grant of summary judgment in Bard's favor for any of Mr. Keen's claims.

Finally, the Court addresses Mr. Keen's motion for leave to submit the testimony of a Bard engineer communicating that electropolishing might have (or might not have) made the G2 more fracture resistant. Bard opposes this motion on the grounds that Mr. Keen waited too long to submit it. Acknowledging that Rule 56(e)(1) provides that the Court may grant "an opportunity to properly support or address" a fact which a party previously failed to properly assert, FED. R. CIV. P. 56(e)(1), the Court grants Mr. Keen's motion for leave to submit this testimonial evidence.

LEGAL STANDARD

A court can grant a motion for summary judgment "if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." FED. R. CIV. P. 56(a). An issue is "genuine" if there is a sufficient evidentiary basis on which a reasonable jury could return a verdict for the non-moving party. *Kaucher v. Cnty. of Bucks*, 455 F.3d 418, 423 (3d Cir. 2006) (citing *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986)). A factual dispute is "material" if it might well affect the outcome of the case under governing law. *Id.* (citing *Anderson*, 477 U.S. at 248). Under Rule 6 of the Federal Rules of Civil Procedure, the Court must view the evidence presented in the motion in the light most favorable to the non-moving party and draw all evidence in that party's favor. *Id.* However, "[u]nsupported assertions,

conclusory allegations, or mere suspicions are insufficient to overcome a motion for summary judgment." *Betts v. New Castle Youth Dev. Ctr.*, 621 F.3d 249, 252 (3d Cir. 2010).

The movant bears the initial responsibility for informing the Court of the basis for the motion for summary judgment and identifying those portions of the record that demonstrate the absence of a genuine issue of material fact. *Celotex Corp. v. Catrett*, 477 U.S. 317, 322-23 (1986). Where the non-moving party bears the burden of proof on a particular issue, "the burden on the moving party may be discharged by 'showing'—that is, pointing out to the district court—that there is an absence of evidence to support the non-moving party's case." *Id.* at 325. After the moving party has met its initial burden, the non-moving party then must set forth specific facts showing that there is a genuinely disputed factual issue for trial by "citing to particular parts of materials in the record, including depositions, documents, electronically stored information, affidavits or declarations, stipulations . . . , admissions, interrogatory answers, or other materials" or by "showing that the materials cited do not establish the absence or presence of a genuine dispute." FED. R. CIV. P. 56(c). Summary judgment is appropriate if the non-moving party fails to rebut by making a factual showing "sufficient to establish the existence of an element essential to that party's case, and on which that party will bear the burden of proof at trial." *Celotex*, 477 U.S. at 322.

DISCUSSION

Mr. Keen brings strict liability and negligence claims alleging design defect, manufacturing defect, and failure-to-warn, a negligent misrepresentation claim, and an implied warranty of merchantability claim and seeks punitive damages. Bard contends that the Court should grant summary judgment in its favor as to all of Mr. Keen's claims. The Court addresses each claim below.

I. Strict Liability Claims

Mr. Keen's brings strict liability claims alleging defects in design, manufacturing, and failure-to-warn against Bard. In general, § 402A of the Restatement (Second) of Torts governs strict liability claims. *Tincher v. Omega Flex, Inc.*, 104 A.3d 328, 394-99 (Pa. 2014); *Webb v. Zern*, 220 A.2d 853, 854 (Pa. 1966). Under § 402A, a plaintiff may recover based on a strict liability theory if his or her injury was caused by a product in "a defective condition unreasonably dangerous to the user or consumer." Restatement (Second) of Torts § 402A; *see also Phillips v. A-Best Prods. Co.*, 665 A.2d 1167, 1170 (Pa 1995). A "defective condition" can be established by showing that a product suffered from a design defect, failure-to-warn, or manufacturing defect. Restatement (Second) of Torts § 402A. However, comment k of Section 402A provides that manufacturers of "unavoidably unsafe products" are exempted from strict liability when the product at issue is "properly prepared, and accompanied by proper directions and warning, is not defective, nor is it unreasonably dangerous." Restatement (Second) of Torts 402A § cmt. k (emphasis in original). Comment k applies to "many . . . drugs, vaccines, and the like, many of which . . . cannot legally be sold except to physicians, or under the prescription of a physician." *Id.*

Bard argues that Mr. Keen's strict liability claims are barred as a matter of law pursuant to comment k to § 402A of the Restatement (Second) of Torts. Mr. Keen, however, insists that in order for comment k to apply, Bard must prove—and has failed to prove—that the G2X filter is unavoidably unsafe.

The Pennsylvania Supreme Court has long interpreted comment k to bar strict liability claims in the context of prescription *drugs*. *See, e.g.*, *Lance v. Wyeth*, 85 A.3d 434, 453 (Pa. 2014) ("[F]or policy reasons this Court has declined to extend strict liability into the prescription drug

arena[.]"); *Hahn v. Richter*, 673 A.2d 888, 891 (Pa. 1996) ("*Incollingo* and *Baldino*, as well as comments k and j, make it clear that where the adequacy of warning associated with prescription drugs is at issue, the failure of the manufacturer to exercise reasonable care to warn of dangers, *i.e.*, the manufacturer's negligence, is the only recognized basis of liability."); *Incollingo v. Ewing*, 282 A.2d 206, 219-20 (Pa. 1971) (holding that manufacturers of drugs, rather than being held strictly liable, can only be held liable for a failure to exercise reasonable care to warn about risks attendant to a product); *Baldino v. Castagna*, 478 A.2d 807, 810 (Pa. 1984) (reaffirming *Incollingo* holding). Mr. Keen in part argues that this bar against strict liability claims is inapplicable here "because Bard is a medical device manufacturer, not a drug manufacturer." Pl.'s Resp. in Opp'n at 11 (Doc. No. 71).

The Pennsylvania Supreme Court has yet to specifically address comment k's application to prescription medical *devices*. "In the absence of a controlling decision by the Pennsylvania Supreme Court, a federal court applying that state's substantive law must predict how Pennsylvania's highest court would decide [the] case." *Berrier v. Simplicity Mfg., Inc.*, 563 F.3d 38, 45-46 (3d Cir. 2009).

Although the Pennsylvania Supreme Court has yet to address this inquiry, the Superior Court of Pennsylvania held in *Creazzo v. Medtronic, Inc.*, 903 A.2d 24, 31 (Pa. Super. Ct. 2006), that those plaintiffs could not pursue a strict liability claim against the manufacturer of an implantable neurological electrical stimulation device. *Id.* at 26, 31. In so holding, it reasoned that it "[found] no reason why the same rational[e] applicable to prescription drugs may not be applied to medical devices." *Id.* at 31. The Court's colleague, Judge Eduardo Robreno, has explained in *Rosenberg v. C.R. Bard, Inc.*, 387 F. Supp. 3d 572 (E.D. Pa. 2019), that the plain language of comment k, which focuses on products which cannot be legally sold except to

physicians or with a physician's prescription, further suggests that "no meaningful distinction can be drawn between prescription drugs and prescription medical devices."[9] *Id.* at 577. Therefore, it is not surprising that a subcommittee note to the Pennsylvania Bar Institute's Suggested Standard Civil Jury Instructions notes in regard to the duty to warn in the prescription drug and medical device context that "Pennsylvania courts have declined to apply strict liability in cases involving prescription drugs *and medical devices*, in accordance with comment k to the Restatement (Second) of Torts § 402A." Pennsylvania Bar Institute, *Pa. Suggested Standard Civil Jury Instruction*, subcommittee note to § 23.00 (May 2015) (emphasis added).[10] It is not surprising that many district courts applying Pennsylvania law have similarly predicted that the Pennsylvania Supreme Court would likely extend its bar of strict liability of prescription drug claims to prescription medical device claims.[11]

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[9] The Court finds Judge Robreno's well-reasoned and comprehensive *Rosenberg* opinion to be especially instructive and helpful here.

[10] Pennsylvania courts often favorably cite the Pennsylvania Bar Institute's Suggested Standard Civil Jury Instructions for matters of law. *See, e.g.*, *Thomas v. Monro Muffler, Inc.*, 1949 WDA 2016, 2018 WL 1386825, at *3 (Pa. Super. Ct. Mar. 20, 2018) (finding that the trial court did not err by instructing "the jury consistent with the Pennsylvania Standard Civil Jury Instructions on all issues touched upon and relative to [the plaintiff's] case").

[11] *Terrell v. Davol, Inc.*, No. 13-5074, 2014 WL 3746532, **3-5 (E.D. Pa. July 30, 2014) (dismissing plaintiff's strict liability claim based on an alleged manufacturing defect of medical mesh device on the basis that such a claim is barred under Pennsylvania law); *McPhee v. DePuy Orthopedics, Inc.*, 989 F. Supp. 2d 451, 460-61 (W.D. Pa. 2012) (dismissing plaintiff's strict liability claims regarding an artificial hip because it predicted that that the Supreme Court of Pennsylvania would extend *Hahn*'s holding to medical devices); *Horsmon v. Zimmer Holdings, Inc.*, No. 11-1050, 2011 WL 5509420, at *2 (W.D. Pa. Nov. 10, 2011) (dismissing strict liability claims regarding artificial hip implant based on reasoning that *Hahn*'s bar to strict liability claims for medical drugs extends to medical devices); *Esposito v. I-Flow Corp.*, No. 10-3883, 2011 WL 5041374, at *4 (E.D. Pa. Oct. 24, 2011) (dismissing strict liability claim against manufacturer of pain pump catheters pursuant to comment k of § 402A); *Soufflas v. Zimmer, Inc.*, 474 F. Supp. 2d 737, 750 (E.D. Pa. 2007) (granting summary judgment concerning tibial insert, reasoning that the Pennsylvania Supreme Court "would extend § 402A's comment k to exclude prescription medical devices from strict liability"); *Parkinson v. Guidant Corp.*, 315 F. Supp. 2d 741, 747 (W.D. Pa. 2004) ("[T]he Pennsylvania Supreme Court has ruled that § 402A strict liability is precluded *entirely* for prescription drugs, and, presumably by extension, prescription medical devices. . . . Instead, the caveats set forth in comment K are to be evaluated under negligence, not strict liability, principles") (emphasis in original).

Mr. Keen argues that for comment k to apply, there must first be a determination that the device was "unavoidably unsafe" and that Bard has failed to prove that the G2X filter is unavoidably unsafe, or alternatively, that there is, at a minimum, a question of fact as to whether the G2X filter was unavoidably unsafe. In doing so, Mr. Keen primarily cites a myriad of cases assessing comment k pursuant to other states' law and *Beard v. Johnson and Johnson, Inc.*, 41 A.3d 823 (Pa. 2012). Mr. Keen cites *Beard* for the proposition that the court must first make a threshold determination as to whether the utility of the G2X filter is outweighed by the risk. *Id.* at 831. That case, however, is distinguishable because it concerned a strict liability claim for a design defect regarding a surgical tool; known as an endocutter, which is "a linear cutting and stapling instrument, used in place of traditional scalpel-and-suture techniques in various surgical applications." *Id.* at 834-25. As Judge Robreno observed in *Rosenberg*, a surgeon's tool is distinguishable from a medical device implanted into the body only upon obtaining a physician's prescription. 387 F. Supp. 3d at 578 n.2. This distinction helps to explain why comment k was not discussed in *Beard*. *Id.* It is not obvious—or even perhaps logical—that the mere fact that a device is used in a medical context would render it a prescription medical device for purposes of comment k. The Court is unpersuaded by the inapplicable case law cited by Mr. Keen. Rather, the Court joins its many colleagues to predict that it is appropriate to apply comment k to Mr. Keen's strict liability claims in the absence of a comprehensive factual analysis assessing the safety of the G2X filter.

Alternatively, Mr. Keen argues that even if comment k's immunity is applicable here, it does not apply to his manufacturing defect claim. Although the Pennsylvania Supreme Court has

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This is not an exhaustive list. *But see Schrecengost v. Coloplast Corp.*, 425 F. Supp. 3d 448, 466 (W.D. Pa. 2019).

applied comment k to bar strict liability for claims alleging design defect and failure-to-warn,[12] it has not expressly done so for manufacturing defect in the prescription drug and device context. In the wake of the Pennsylvania Supreme Court's silence on the issue of whether state law bars strict liability claims for manufacturing defects in the prescription product arena, district courts have reached mixed results in predicting whether such claims are barred pursuant to the application of comment k.

In advancing his argument, Mr. Keen points out that one unpublished decision from this district commented, "Courts and commentators . . . generally agree that comment k's immunity from strict liability does not extend to manufacturing defects." *Doughtery v. C.R. Bard, Inc.*, No. 11-6048, 2012 WL 2940727, at *5 (E.D. Pa. July 18, 2012). However, this cite is misleading, considering the only support for this proposition assesses how comment k has been applied in other jurisdictions outside of Pennsylvania. *Id.* (citing cases assessing the application of comment k under the law of Washington, California, Idaho, Kansas, and Utah). Mr. Keen also relies on a passage from *Wagner v. Kimberly-Clark Corp.*, 225 F. Supp. 3d 311 (E.D. Pa. 2016), which cites *Beard* to support its prediction that the Pennsylvania Supreme Court would permit strict liability manufacturing claim. The Court again rejects Mr. Keen's reliance on *Beard* for the reasons set forth above. *See supra* pp. 13-14. Accordingly, the Court disagrees with Mr. Keen that the Pennsylvania Supreme Court would deviate from its otherwise uniform application of comment k in order to permit strict liability claims based on manufacturing defect theory.[13]

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[12] *See Hahn*, 673 A.2d at 891 (noting negligence as the only basis for liability on the basis of inadequate warnings); *Incollingo*, 282 A.2d at 219 (holding a drug manufacturer not strictly liable "merely because of the dangerous propensities of the product").

[13] Perhaps the more common argument advanced by parties in support of this proposition relies on the Superior Court of Pennsylvania's 2010 decision in *Lance v. Wyeth*, 4 A.3d 160 (Pa. Super. Ct. 2010). Courts and parties have cited language in that decision stating that "a plaintiff may advance only two possible strict liability claims," one of which apparently being a manufacturing defect claim. *Id.* at 165.

Finally, the Court notes that some district courts have pointed to the Pennsylvania Supreme Court's decision in *Tincher v. Omega Flex, Inc.*, 104 A.3d 328 (Pa. 2014), as standing for the general proposition that "[n]o product is expressly exempt" from strict liability. *Id.* at 382.[14] As Judge Robreno stated in *Rosenberg*, however, the Pennsylvania Supreme Court noted a specific exception to this proposition put forth in *Tincher* by immediately following the general statement with a "but see" citation to *Hahn v. Richter*, 673 A.2d 888 (Pa. 1996). *Rosenberg*, 387 F. Supp. 3d at 580. In doing so, that court signaled that strict liability is still not a recognized basis for liability for, at the very least, claims regarding the adequacy of a prescription drug's warnings. *Id.* (citing *Tincher*, 104 A.3d at 367 n.13, 396). "Therefore, nothing in *Tincher* reopens the door to strict liability claims for prescription drugs or prescription medical devices, a door *Hahn* had firmly closed." *Id.* at 580-81.

In sum, the Court predicts that the Pennsylvania Supreme Court would apply comment k to all of Mr. Keen's strict liability claims. Therefore, the Court grants Bard summary judgment in its favor regarding Mr. Keen's strict liability claims alleging defects in design, manufacturing, and failure-to-warn.

II. Negligence Claim

Mr. Keen alleges negligence against Bard, basing his claim upon design defect, manufacturing defect, and failure-to-warn theories. "To prevail in a negligence action, a plaintiff

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As Judge Robreno commented in *Rosenberg*, however, the shelf-life on that decision was short-lived, and the Pennsylvania Supreme Court's observations articulated in *Lance* made clear that "the Superior Court's observation that a plaintiff may bring a strict liability manufacturing defect claim in the prescription drug context is entitled to no weight." *Rosenberg*, 387 F. Supp. 3d at 580.

[14] Mr. Keen did not cite *Tincher* in his briefing, instead citing it for the first and only time in a "notice of supplemental authority in support of his response to Defendants' motion for summary judgment" submitted months after the parties' briefing was due. (Doc. No. 112). Even so, the Court deems it important to address this case for the sake of thoroughness.

'must show that the defendant had a duty to conform to a certain standard of conduct, that the defendant breached that duty, that such breach caused the injury in question, and actual loss or damage.'" *Berrier*, 563 F.3d at 61 (quoting *Phillips v. Cricket Lighters*, 841 A.2d 1000, 1008 (Pa. 2003)). Bard moves for summary judgment in its favor concerning all of Mr. Keen's negligence theories. The Court addresses each in turn.

A. Negligent Design

The parties' dispute concerning Mr. Keen's negligent design claim is twofold. First, the parties dispute what the applicable standard duty of care is for assessing Mr. Keen's negligent design claim. Second, the parties disagree as to whether Mr. Keen has presented sufficient evidence to create a jury issue in order to survive summary judgment on this issue.

Concerning the applicable standard inquiry, Bard contends that *Lance v. Wyeth*, 85 A.3d 434 (Pa. 2014), makes clear that "[u]nder Pennsylvania law, pharmaceutical companies violate their duty of care if they introduce a drug into the marketplace, or continue a previous tender, with actual or constructive knowledge that the drug is too harmful to be used by anyone." *Id.* at 461. Mr. Keen, however, argues that the Pennsylvania Supreme Court did not "intend[] to limit negligence claims to only those products too dangerous to be taken by anyone." *Kramme v. Zimmer, Inc.*, No. 11-916, 2015 WL 4509021, at *6 (M.D. Pa. July 24, 2015); *see also Crockett v. Luitpold Pharms. Inc.*, No. 19-276, 2020 WL 433367, at *11 (E.D. Pa. Jan. 28, 2020) (limiting *Lance II* to its facts and declining "to apply such a burdensome standard").

Although no appellate court in Pennsylvania has commented on the scope of *Lance*'s holding, the Pennsylvania Bar Institute and other courts have. For instance, the Pennsylvania Bar Institute's suggested jury instructions support Bard's proposition. Pennsylvania Bar Institute, *Pa. Suggested Standard Civil Jury Instructions*, at § 23.40 (4th ed. 2018 supp.) ("A [pharmaceutical]

[medical device] [company] [partnership] that supplies a [prescription drug] [medical device] that it knew or reasonably should have known is too dangerous to be used by anyone, violates its duty of care.").[15]

Moreover, the Court's colleague, Judge Gerald Pappert, recently resolved a similar dispute in *Ebert v. C.R. Bard, Inc.*, No. 12-1253, ___ F. Supp. 3d ___, 2020 WL 2332060 (E.D. Pa. May 11, 2020). In that case, the plaintiff argued for a much broader standard than the one Bard advocates for by relying on the following language from *Lance*: "[T]he law of negligence establishes a duty, on the part of manufacturers, which can be viewed on a continuum from the requirements of: a warning of dangers, through a stronger warning if justified by the known risks, through non-marketing or discontinuance of marketing when it becomes or should become known that the product should not be used in light of its relative risks." 85 A.3d at 459-60.[16] As Judge Pappert explained in *Ebert*, *Lance*'s continuum language is merely dicta explaining the range of duties of care applicable to negligence claims generally. 2020 WL 2332060, at *4. In fact, the continuum language refers to negligence claims brought under negligent failure-to-warn, negligent design defect, and negligent marketing claims, but omits specifics concerning a negligent design claim. *Id.* The Court agrees with Bard that this language and Mr. Keen's brief assertion that the *Lance* standard ought not apply do not lessen the duty of care clearly articulated by the

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[15] Along these lines, the Pennsylvania Bar Institute included a subcommittee note stating that "the Supreme Court of Pennsylvania [in *Lance*] held that the plaintiff was entitled to pursue claims for negligent product design, negligence in marketing, and continuing to market a prescription drug or medical device where the manufacturer had actual or constructive notice that it was too dangerous to be used by any patient." *Id.*

[16] *Kramme v. Zimmer, Inc.*, No. 11-916, 2015 WL 4509021 (M.D. Pa. July 24, 2015), a case in which Mr. Keen relies on here, cited the same language in rejecting the application of Bard's proposed standard. *Id.* at *6.

Pennsylvania Supreme Court. Therefore, the Court will apply *Lance*'s "too dangerous to be used by anyone" duty of care standard in assessing Mr. Keen's negligent design claim.

Mr. Keen alternatively argues that even if the standard articulated in *Lance* applies, he has presented sufficient evidence that the factfinder may determine that Bard introduced a medical device in the marketplace with actual or constructive knowledge that it was too harmful to be used by anyone. The Court agrees that there is material in the record to raise such an issue. In support of his claim, Mr. Keen cites a substantial array of evidence, particularly focusing on evidence concerning the Recovery and G2 filters.[17]

Mr. Keen first focuses on evidence concerning Bard's Recovery filter. In the sole pre-clinical study for the Recovery filter, Canadian interventional radiologist Dr. Murray Asch observed two fractures, two tilts, one migration, and one perforation of the IVC after implanting 32 patients. After Dr. Asch reported these complications, the Canadian Institutional Review Board suspended the Recovery study. Dr. Asch testified that his study should never have been used to seek FDA market clearance for the Recovery filter in the United States. Bard communicated to Dr. Asch that there was a potential weakness at the site of the weld as well as a potential for increasing the robustness, and that it would try to alter the design or manufacturing process in order to prevent future filter fractures. Mr. Keen suggests that there is a dearth of evidence supporting that Bard ever did so. Moreover, Bard's Vice-President of Quality Assurance testified that according to Bard's policy and procedures, the risk of the Recovery filter was unacceptable and required correction.

Mr. Keen also presents evidence regarding problems associated with the G2 filter. For

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[17] The Court is not convinced that some of the propositions Mr. Keen asserts are actually demonstrated by the record cites advanced by his counsel in support of those propositions. Accordingly, the Court only cites evidence appropriately supported by the provided citations.

instance, in December 2005, Bard's Corporate Clinical Affairs Director's questioned why doctors would be using the G2 rather than the Simon Nitinol filter which "has virtually no complaints associated with it". Pl.'s Ex. LL (Doc. No. 98-9). Approximately two months later, a Bard Health Hazard Evaluation characterized the "severity" of the migration problems with the G2 as "critical", stating in part that a "high percentage of caudal migrations [were] accompanied by significant filter tilting and limb displacement." Pl.'s Ex. 77 (Doc. No. 104-17).[18] The following month, Bard's internal failure mode and effects analysis demonstrated that the G2 filter's propensity for caudal migration represented an "unacceptable risk". Pl.'s Ex. 81 (Doc. No. 105-1). Moreover, the medical monitor for Bard's clinical retrievability study for the G2 filter expressed concern regarding the rate of tilt in the study and "thought that Bard may want to consider a redesign based on this information." Pl.'s Ex. 86, at 803 (Doc. No. 105-6). By June 2008, Bard identified a need to make material improvements to the G2 filter to reduce migration, tilt, fracture, and perforation.[19] By November 2008, Bard was aware that, from reported events of filter fracture reported, the G2 had higher rates of caudal migration, tilt, and perforation involved in those events than those involved in the Recovery filter.

Concerning the filter implanted in Mr. Keen, Dr. McMeeking opined that the tilting and fractures Mr. Keen's filter resulted from inadequate design and an inadequate level of testing and analyses prior to implantation. McMeeking Oct. 2014 Report, Pl.'s Ex. CCC, at 48 (Doc. No. 99-5); McMeeking Jan. 2015 Report, Pl.'s JJJ, 48-49 (Doc. No. 99-12).

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[18] Bard points out that Mr. Keen did not suffer from a caudal migration complication. But if the applicable standard assesses whether the product is too dangerous to be used by anyone, it follows that any evidence of any complications could be considered in the factfinder's determination.

[19] By that time, Bard believed that caudal migrations lead to tilts, perforations, and fractures.

Bard makes three arguments as to why the Court should grant summary judgment in its favor as to this claim. First, Bard points out that no regulatory body or medical society has ever stated that the G2X filter should not be used for any class of patients or is otherwise unsafe for use. Although this appears to be true, the Court also does not find this absence of evidence to be dispositive. That would be for a jury to weigh. The Court is unaware of any instruction from the Pennsylvania Supreme Court that a device can only be "too harmful to be used by anyone" if so decreed by a regulatory body or medical society.[20] Second, Bard contends that any evidence concerning the Recovery filter is of no moment because Mr. Keen received a G2X filter, not a Recovery filter. As noted, the Court finds that there is a sufficient connection between the G2X filter and the Recovery filter so that evidence concerning the Recovery filter may help assist the finder of fact in determining whether the G2X is too dangerous to be used by anyone.

Third, Bard insists that Mr. Keen's evidence misses the mark because all IVC filters carry a risk of fracture of up to 10% and that the reported G2X filter fracture rate as of January 2017 was only 0.21%.[21] Mr. Keen raises issue with the 10% figure, reasoning that it was published based exclusively on permanent-only filters and that it is a guideline, not necessarily an industry standard. In any event, Bard's 0.21% fracture rate is based upon years of data postdating Mr. Keen's interactions with the device. From the evidentiary document Bard frequently cites in support of this fracture rate, it is impossible for the Court to discern a fracture rate associated with the filter during the time in which a G2X filter was implanted in Mr Keen. Moreover, the Court questions whether even properly calculated, relevant dueling "statistical" or "mathematical" evidence over the failure rates would be dispositive as to this claim for either party at the summary

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20 The standard is high, but there is no reason to rule that the standard is *that* demanding.

21 According to this January 2017 data, the G2X's highest complication rate was its 0.25% tilt rate.

judgment stage. *Ebert*, 2020 WL 2332060, at *4 n.5 (noting that neither a failure rate of the G2 filter of 0.06%, as Bard alleged, or 31%, as the plaintiff alleged, "is dispositive to the outcome of this or any other of [the plaintiff's] claims").

Therefore, the Court finds it appropriate for a jury to determine whether the G2X filter is too dangerous to be used by anyone. Accordingly, the Court denies Bard's motion as to Mr. Keen's negligence claim based on a design theory.

B. Negligent Failure-to-Warn

Bard argues that Mr. Keen's negligent failure-to-warn claim fails on two separate grounds: that it is barred by the learned intermediary doctrine and that Mr. Keen failed to prove proximate causation.

1. Learned Intermediary Doctrine

Under Pennsylvania law and what is known as the learned intermediary doctrine, "a medical device manufacturer has a duty to warn implanting physicians about the dangers of a medical device, but has no duty to warn patients directly." *McLaughlin v. Bayer Corp.*, 172 F. Supp. 3d 804, 831 (E.D. Pa. 2016) (citation omitted). "Thus, in an action against a drug [or device] manufacturer based upon inadequate warnings, the issue to be determined is whether the warning, if any, that was given to the prescribing physicians was proper and adequate." *Daniel v. Wyeth Pharms., Inc.*, 15 A.3d 909, 924 (Pa. Super. Ct. 2011) (citation omitted).

In Pennsylvania, the adequacy of the manufacturer's warning to the prescribing physician is a question of law. *Mazur v. Merck & Co.*, 964 F.2d 1348, 1366 (3d Cir. 1992) (citing *Mackowick v. Westinghouse Elec. Corp.*, 575 A.2d 100, 102 (Pa. 1990)). In order to be deemed adequate as a matter of law, a warning "must (1) accurately and unambiguously convey the scope and nature of the risk, and (2) state the risk with sufficient specificity." *Schrecengost v. Coloplast Corp.*, 425 F.

Supp. 3d 448, 462 (W.D. Pa. 2019). However, "where fact questions exist" such as "the sufficiency of the warning for a particular risk identified in the label . . . the question of adequacy is one for the jury." *In re Avandia Mktg., Sales Practices and Prods. Liab. Litig.*, 817 F. Supp. 2d 535, 545-46 (E.D. Pa. 2011) (citation omitted). "Facially accurate statements of fact regarding a particular risk are not adequate as a matter of law where there are disputes over whether the warning was sufficiently explicit and detailed." *Rowland v. Novartis Pharms. Corp.*, 34 F. Supp. 3d 556 (W.D. Pa. 2014) (citation omitted). "The adequacy of a warning is determined based on what the manufacturer knew, or should have known, about a given risk at the time the patient was prescribed the medical device, and whether the label warned of that risk." *Ebert*, 2020 WL 2332060, at *6. Typically, expert testimony is required to determine the adequacy of a warning. *Demmler v. SmithKline Beecham Corp.*, 671 A.2d 1151, 1154 (Pa. Super. Ct. 1996).

Bard argues that its warnings provided in the "Instructions for Use" accompanying Mr. Keen's G2X filter were adequate as a matter of law because it generally warned of a risk of fracture, tilt, perforation, and irretrievability.[22] Mr. Keen counters that Bard's warnings were inadequate because they failed to disclose G2X's higher rates of failure when compared to similar filters as well as G2X's risk of serious injury in patients. Bard replies that although Mr. Keen argues that Bard's rates of complication were higher than other filters available on the market, (1) the identified G2X complication rates are at most 0.25% and the filter rate 0.21%;[23] and (2) the

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[22] Bard further argues that its warnings were adequate given Dr. Sacks' knowledge of IVC filters, including his knowledge of the 2001 guidelines' discussion of rates of adverse events. But Dr. Sacks' knowledge of adverse events associated with all IVC filters is just one of many facts that a factfinder could take into consideration when assessing whether a warning is sufficiently explicit and detailed.

[23] Again, Bard relies on a figure that takes into consideration information dating up to January 2017, years after Mr. Keen's implant. *See* Def.s' Reply at 6 (Doc. No. 76).

G2X's Instructions for Use provided a summary of a clinical study involving the G2 filter discussing complication rates of the filter during the study.

The parties' dispute over the sufficiency of the warning is a classic inquiry for the jury to decide. Indeed, other courts have already rejected similar arguments asserted by Bard concerning its IVC filter warnings when applying Georgia's similar learned intermediary doctrine. *See, e.g.*, *Cason v. C.R. Bard, Inc.*, No. 12-1288, 2015 WL 9913809, at **3-5 (N.D. Ga. Feb. 9, 2015) (determining that a reasonable fact finder could conclude, in the face of evidence that Bard's warning failed to disclose that the G2 had significantly higher frequencies of complications than other IVC filters on the market, that the G2 filter's Instructions for Use failed to provide an adequate warning). For instance, when assessing failure-to-warn claims concerning the warnings used for the G2 filter in the MDL, Judge Campbell determined under Georgia law that it was the jury's task to determine whether the warnings at issue were adequate. *See In re Bard Filters Prods. Liab. Litig.*, No. 15-2641, No. 16-474, 2017 WL 5625548, at **2-6 (D. Ariz. Nov. 22, 2017).[24] Because the question of whether Bard provided adequate warnings is an inquiry for the jury to decide rather than the Court, the Court rejects Bard's argument.

2. Proximate Causation

Bard argues Mr. Keen failed to offer sufficient evidence that a different warning would have altered Dr. Sack's decision to use the G2X filter. In Pennsylvania, "proximate cause is not presumed." *Demmler*, 671 A.2d at 1155. Rather, "to create a jury question, the evidence introduced [concerning proximate causation] must be of sufficient weight to establish . . . some reasonable likelihood that an adequate warning would have prevented the plaintiff from receiving the drug." *Id.* (quotation marks and citations omitted).

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[24] The Ninth Circuit Court of Appeal's affirmed Judge Campbell's denial of summary judgment as to that plaintiff's failure-to-warn claim on August 13, 2020. Pl.'s Notice (Doc. No. 121).

Bard argues that Dr. Sacks' testimony that he does not recall whether he read the G2X filter's Instructions for Use is dispositive because the jury would have to speculate that Dr. Sacks would have read the warning that Mr. Keen faults Bard for not providing. Bard's targeted focus on this testimony, however, misses the mark. Mr. Keen stresses that Bard's sales representative also provided Dr. Sacks oral information in addition to the written information. Sacks Dep. at 11:14-16 (Doc. No. 97-3). Dr. Sacks testified that he relies on "the manufacturer to tell [him] as much information as [it] ha[s] available that would be relevant to [his] placing the filter[,]" *id.* at 96:23-97:1, and that he expects the manufacturer to provide information concerning known adverse events with the product, *Id.* at 97:17-20. Dr. Sacks recalled communicating his concerns about the Recovery filter and being "told that the G2 would address those problems of fracture and migration. I don't recall that the G2X had substantial differences from the function of the G2 other than the hook at the apex." *Id.* at 107:5-10. Mr. Keen's argument follows that a reasonable jury could conclude that Dr. Sacks relied on the sales representative's oral communications, which omitted pertinent comparative information, in deciding to implant the G2X filter in Mr. Keen and that Dr. Sacks would have chosen an alternative IVC filter if given an adequate warning.

In response, Bard contends that the following testimony of Dr. Sacks demonstrates that the inclusion of comparative complication rates between the G2X and other filters still would have not altered his decision to implant the G2X filter in Mr. Keen:

> Q: If you had learned that the G2X had higher rates of fractures than any other filter on the market, would you have still used that for Harry Keen? . . .
>
> A: Highest rates on the market is a relative term. If I knew that the fracture rate of the G2 was three percent and another filter that would accomplish the same job would be two percent, that would probably not make a difference. If I heard that the fracture rate were twenty-five percent, and I'm just arbitrarily saying that, and the comparable device would be two percent, that would be likely to alter my filter choice. It would also be useful to know the rate of

> clinical complications from those fractures. Fractures in devices can by asymptomatic and of no relevance.

Id. at 107:11-14; 107:22-108:12. Thus, according to Bard, "a 0.25%[25] difference (or less) between complication rates that [Mr. Keen] argues Bard concealed, as a matter of law, would have made no difference on [Dr. Sacks'] decision either." Def.s' Reply at 8 (Doc. No. 76).

But this argument is based on Bard's insistence that its proffered G2X complication rates, which are based on data as late as January 2017, are the correct rates of complications. Mr. Keen contends that Bard's .21% fracture rate is "cherry-picked", "unreliable", and "untrustworthy." Pl.'s Post-Oral Argument Supp. Brief at 2 (Doc. No. 119). When asked to provide a definitive dueling fracture rate, Mr. Keen's attorney proffered a calculation of a 21% fracture rate based on what Bard opportunistically, but aptly, dismissed as "lawyer math."[26] Even so, the Court takes issue with Bard's insistence that the fracture rate is definitively 0.21 percent, as it is based on years of data postdating Mr. Keen's implant. The Court will not conclude that no reasonable juror could find in Mr. Keen's favor based on Bard's reliance on data which factors in years' worth of extraneous data and provides no discernable way to separate the timely data from the untimely data. Accordingly, the Court rejects Bard's argument that the aforementioned testimony undisputedly demonstrates that a different warning would have altered Dr. Sacks' decisionmaking. Therefore, the Court denies Bard's motion as it pertains to Mr. Keen's negligent failure-to-warn claim.

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[25] At oral argument, the parties focused on the reported 0.21% fracture rate as of January 2017, instead of the 0.25% rate Bard cited in its reply brief.

[26] This is not to say that Mr. Keen's issue with Bard purportedly omitting a substantial majority of unreported adverse events should go unnoticed. But complex mathematical calculations relied upon in a court of law ought to be based on evidentiary support, not an attorney's apparent understanding of "basic math."

C. Negligent Manufacturing

To prove a negligent manufacturing claim, a plaintiff must show that "(1) the manufacturer owed a duty to the plaintiff, (2) the duty was breached, and (3) such a breach was the proximate cause of plaintiff's injuries." *Soufflas v. Zimmer, Inc.*, 474 F. Supp. 2d 737, 753 (E.D. Pa. 2007) (citing *Cricket Lighters*, 841 A.2d at 1008). To demonstrate a breach of duty, a plaintiff must show that a defendant "failed to exercise due care in manufacturing or supplying the product. Put another way, [a p]laintiff must come forward with evidence that [a defendant] . . . deviated from the general standard of care expected under the circumstances." *Id.* at 754 (citing *Taylor v. Danek Med., Inc.*, No. 95-7232, 1998 WL 962062, *11 (E.D. Pa. Dec. 29, 1998)).

Bard advances two bases for granting summary judgment in its favor on this claim. First, Bard insists that Mr. Keen failed to adduce that the G2X filter differed from its intended design. *See Cricket Lighters*, 841 A.2d at 1019 (Saylor, J., concurring) (noting that manufacturing defects "are deemed present when a product fails to conform to its intended design").

According to Mr. Keen, his claim should survive because Bard failed to exercise due care in manufacturing the G2X filter, as is demonstrated by Dr. Robert Ritchie's expert opinion that the IVC filters he studied during his comparative examination "had been improperly designed and manufactured such that they were unable to endure the physiological stresses and strains that they experienced *in vivo*." Ritchie Report, at 1, Pl.'s Ex. RRR (Doc. No. 99-19). After examining various Recovery, G2, and G2X filters and the G2X filter implanted in Mr. Keen under scanning electron microscopy, Dr. Ritchie opined that Bard's filters (1) were lacking an appropriately rounded chamfer on the edge of the filter sleeve (an alleged manufacturing and/or design defect which would radically increase local stresses); (2) had poor surface condition of the arms (an alleged manufacturing defect which locally promotes the initiation of fatigue cracks in these

components); and (3) had rough centerless grinding markings on the taped foot regions (an alleged manufacturing defect promoting fatigue failure of the foot which can lead to filter tilting and migration). Bard contends that the fact that the G2X filter implanted in Mr. Keen contained the same irregularities as the other studied filters demonstrates that nothing went awry in the manufacturing process.

Although the Pennsylvania Bar Institute's Suggested Standard Civil Jury Instructions do not set forth proposed instructions for a negligent manufacturing claim, it cites the following as the "traditional definition of manufacturing defect": "a manufacturing or production defect is readily identifiable because a defective product is one that differs from the manufacturer's intended result or from other ostensibly identical units of the same product line." Pennsylvania Bar Institute, *Pennsylvania Suggested Standard Civil Jury Instructions*, at § 16.15 (4th ed. 2018 supp.) (citing *Barker v. Lull Eng'g Co.*, 573 P.2d 443, 454 (Cal. 1978)). Although the evidence presented at summary judgment does not necessarily suggest that Mr. Keen's G2X filter differed from other G2X or other Bard filters, it does suggest that a jury could find that it differed from Bard's intended result for the filter to remain stable and maintain its integrity within the IVC.

Second, Mr. Keen asserts that the filter's poor surface conditions could have been reduced through the electropolishing process, which Bard performed for its Eclipse filter. Specifically, Dr. Ritchie determined that "[i]t is clear that the initiation of the fatigue crack that caused this leg to fracture was promoted by stress concentrations associated with circumferential grinding markings used to machine the taper in the foot region [the area of one of Mr. Keen's fractures]. These represent a severe manufacturing defect that could have been easily removed during manufacture by polishing or better still electropolishing the surface of the device." Ritchie Report, at 23-24,

Pl.'s Ex. RRR (Doc. No. 99-19).[27] Bard counters that (1) the electropolished Eclipse filter had a higher fracture rate than the G2 filter; (2) there is no evidence that the Eclipse filter was more fracture resistant than the G2X filter; and (3) that its data shows that the fracture rate for the electropolished Eclipse filter, as of January 2017, was 0.17% compared to 0.21% for the G2X filter. Moreover, Dr. McMeeking testified that "electropolishing increases the fatigue limit [of the G2X filter] by a modest amount, by about .2 percent of strain. And therefore, compared to the levels of strain which occur in the Eclipse Filter, this increase is quite marginal and, therefore not enough to fend off the problems of fatigue that the [G2X] was experiencing." *Jones v. Bard* May 16, 2018 Trial Tr., at 396:7-14, Def.s' Ex. C (Doc. No. 76-3). Although the evidence Bard directs the Court's attention to may certainly persuade a factfinder to find in Bard's favor as to this claim, the Court finds it more appropriate for such a determination to be made by a jury, not the Court. Therefore, the Court denies Bard's motion as to the negligent manufacturing claim.

III. Breach of Implied Warranty of Merchantability Claim

Bard argues that Mr. Keen's implied warranty of merchantability claim fails because Pennsylvania law does not impose any implied warranty of merchantability for unavoidably unsafe products. Many courts have recognized that the theories of strict liability and breach of implied warranty of merchantability "'are parallel theories of recovery, one in contract and the other in tort." *Doughtery*, 2012 WL 2940727, at *7 (citation omitted).

In *Makripodis by Makripodis v. Merrell-Dow Pharms., Inc.*, 523 A.2d 374 (Pa. Super. Ct. 1987), the Pennsylvania Superior Court held that breach of implied warranty claims for prescription drugs should be treated in the same manner as strict liability claims for prescription

[27] Mr. Keen's suggestion is also based on the testimony from Bard's director of manufacturing communicating that Bard was hopeful that electropolishing the Eclipse filter could enhance fracture resistance. *See, e.g.*, Ferrari Dep. at 164:8-15, Pl.'s Ex. NN (Doc. No. 98-11).

drugs: precluded pursuant to comment k of § 402A. *Id.* at 376-77. Many federal courts have followed *Makripodis* by dismissing breach of implied warranty of merchantability claims essentially for the same reasons that they precluded strict liability claims. *See Terrell v. Davol, Inc.*, No. 13-5074, 2014 WL 3746532, *6 (E.D. Pa. July 30, 2014) (collecting case). Mr. Keen counters by acknowledging that courts which have declined to conclude that comment k precludes strict liability claims for prescription devices have similarly declined to dismiss implied warranty of merchantability claims. Thus, both parties seem to agree that the Court's determination as to the implied warranty of merchantability claim should mirror its determination as to the strict liability claims.

Thus, the Court grants Bard summary judgment in its favor as to Mr. Keen's implied warranty of merchantability claim essentially for the same reasons that it granted summary judgment in Bard's favor for the strict liability claims.

IV. Negligent Misrepresentation Claim

A plaintiff must establish the following four elements to establish a negligent misrepresentation claim in Pennsylvania: "(1) a misrepresentation of a material fact; (2) made under circumstances in which the misrepresenter ought to have known its falsity; (3) with an intent to induce another to act on it; and (4) which results in injury to a party acting in justifiable reliance on the misrepresentation." *Bortz v. Noon*, 729 A.2d 555, 561 (Pa. 1999). The defendant must also owe a duty to the injured plaintiff. *Id.* To prevail on this claim, Mr. Keen must show that Dr. Sacks relied upon Bard's omissions when he implanted the G2X filter in Mr. Keen. *See Burton v. Danek Med., Inc.*, No. 95-5565, 1999 WL 118020, at *6 (E.D. Pa. Mar. 1, 1999).

Bard contends that Mr. Keen fails to present any evidence establishing that Bard made a misrepresentation of material fact to Dr. Sacks or that he relied on this misrepresentation when

choosing to treat Mr. Keen with the G2X filter. These arguments largely track the analysis already set forth in addressing the negligent failure-to-warn claim.

Concerning Bard's former argument, Mr. Keen contends that Bard misrepresented information to Dr. Sacks when it omitted pertinent information regarding the safety of the G2X filter, which Bard had available at the time. As for the latter argument, as the Court similarly discussed above in discussion section II.B.2, a reasonable juror could conclude that Dr. Sacks relied on Bard to expressly disclose more accurate, detailed information than what was actually communicated to him about adverse events associated with the G2X filter. Therefore, the Court finds that Mr. Keen's negligent misrepresentation claim survives summary judgment.

V. Punitive Damages Claim

Bard moves to dismiss Mr. Keen's punitive damages claim. Pennsylvania "case law makes it clear that punitive damages are an extreme remedy available in only the most exceptional matters. Punitive damages may be appropriately awarded only when the plaintiff has established that the defendant has acted in an outrageous fashion due to either the defendant's evil motive or his reckless indifference to the rights of others." *Cricket Lighters*, 883 A.2d at 445 (quotation marks and internal citations omitted). Therefore, "the plaintiff must adduce evidence which goes beyond a showing of negligence, evidence sufficient to establish that the defendant's acts amount to 'intentional, willful, wanton or reckless conduct . . . .'" *Id.* at 446 (quoting *SHV Coal, Inc. v. Cont'l Grain Co.*, 587 A.2d 702, 705 (Pa. 1991)). Because the determination of whether a defendant's conduct rises to the level of outrageousness is a role for the finder of fact, the Court should decide the viability of a punitive damages claim "only when no reasonable inference from the facts alleged supports a punitive award." *Soufflas*, 474 F. Supp. 2d at 756 (quotation marks and citations omitted).

Bard argues that Mr. Keen has failed to adduce any evidence demonstrating that Bard's conduct was "outrageous" or motivated by "evil." Mr. Keen contends that the evidence he submitted is enough to, at the very least, demonstrate a factual dispute as to whether punitive damages should be awarded for Bard's purported "outrageous conduct, evil motive, and reckless indifference" as to Mr. Keen's rights. Pl.'s Post-Oral Argument Supp. Brief at 6 (Doc. No. 119). The Court concludes that although the record does not make a claim for punitive damages all that obvious, issuing a ruling on punitive damages is premature at the summary judgment stage. Accordingly, the Court will reserve its determination as to punitive damages for a later date.

CONCLUSION

For the foregoing reasons, the Court grants in part and denies in part Bard's motion for summary judgment. Specifically, the Court grants summary judgment in favor of Bard as to the strict liability and breach of implied warranty of merchantability claims, but denies summary judgment as to the negligence and negligent misrepresentation claims. The Court also reserves its determination as to punitive damages for a later date. An appropriate order follows.

BY THE COURT:

GENE E.K. PRATTER
UNITED STATES DISTRICT JUDGE